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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,741	03/26/2004	Donald B. Borders	660081.425C1	9685
7278	7590	04/10/2006		
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			EXAMINER RUSSEL, JEFFREY E	
			ART UNIT	PAPER NUMBER

1654

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/810,741

Applicant(s)

BORDERS ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,5-9,16-22 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5-9,16-22,24 and 26 is/are rejected.
- 7) ☒ Claim(s) 25 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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1. The terminal disclaimer filed February 28, 2006 has been approved.
2. Changes were made to claim 17 without the changes being marked as required by 37 CFR 1.121(c)(2). In particular, the charge signs "2+" for each divalent cation have been changed from superscripts to regular case characters without marking the changes. Any future amendments to the claims should be carefully checked to ensure compliance with the amendment rule.
3. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 26 is unclear because it requires the lipopeptide antibiotic to be extracted from the aqueous solution with an aqueous base solution, whereas the independent claim upon which claim 26 depends requires the lipopeptide antibiotic to be extracted from the aqueous solution with an organic solvent. It is therefore unclear what is to be used to extract the lipopeptide antibiotic from the aqueous solution. Note that, in comparison to claim 25 of U.S. Patent No. 6,716,962 upon which instant claim 26 may be based, claim 26 is missing a limitation.
4. Claims 1, 5-9, 16-18, 22, and 24 are directed to an invention not patentably distinct from claims 1-15 of commonly assigned U.S. Patent No. 6,511,962. Specifically, the claims of the '962 patent clearly anticipate instant claims 1, 5-8, 16-18, 22, and 24. Laspartomycin is a derivative of the specific lipopeptide antibiotics recited in instant claims 1, 5-7, and 24 because laspartomycin, like the specific lipopeptide antibiotics, has a similar structure (e.g., a cyclic peptide core, a lipid substituent, and free carboxylic acid groups) and a similar activity (e.g., antibiotic activity). Note that Applicants have not defined "derivative" so as to require any

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particular degree of similarity between the derivative and the specific lipopeptide antibiotics recited in instant claims 1, 5-7, and 24. With respect to instant claim 9, while the '962 patent does not claim the divalent cation ratio, it would have been obvious to one of ordinary skill in the art to determine all operable and optimal divalent cation ratios for the corresponding method step claims in the '962 patent because reactant ratio is an art-recognized result-effective variable which is routinely determined and optimized in the chemical and extraction arts.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned U.S. Patent No. 6,511,962, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

5. Instant claims 1, 5-9, 16-22, and 24-26 are deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/286,254 because the '254

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application, under the test of 35 U.S.C. 112, first paragraph, discloses the instant claimed invention.

Instant claims 1, 5-9, 16-22, and 24-26 are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of application serial no. 09/760,328 because the '328 application, under the test of 35 U.S.C. 112, first paragraph, does not disclose purifying lipopeptide antibiotics which are the specific derivatives recited in instant claims 1, 5-7, and 24.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1, 5-8, 16-22, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,511,962. The claims of the '962 patent clearly anticipate instant claims 1, 5-8, 16-18, 22, and 24. Laspartomycin is a derivative of the specific lipopeptide antibiotics recited in instant claims 1, 5-7, and 24 because laspartomycin, like the specific lipopeptide antibiotics, has a similar structure (e.g., a cyclic peptide core, a lipid substituent, and free carboxylic acid groups) and a similar activity (e.g., antibiotic activity). Note that Applicants have not defined "derivative" so as to require any particular degree of similarity between the derivative and the specific lipopeptide antibiotics recited in instant claims 1, 5-7, and 24. In addition, Examples 6 and 7 of the '962 patent anticipate instant claims 1, 5-8, 16-22, and 24.

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,511,962. Application of the '962 patent is the same as in the above rejection of claims 1, 5-8, 16-22, and 24. The '962 patent does not teach a molar concentration of divalent cation relative to carboxylate groups in the lipopeptide antibiotic. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and

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optimal divalent cation ratios for the corresponding method step in the '962 patent because reactant ratio is an art-recognized result-effective variable which is routinely determined and optimized in the chemical and extraction arts.

9. Applicant's arguments filed February 28, 2006 have been fully considered but they are not persuasive.

The examiner interprets the new claim language of claims 1 and 24 so that "derivative of" modifies each of the listed specific lipopeptide antibiotics rather than modifying just "zaomycin". In other words, in claims 1 and 24, the lipopeptide antibiotics can be derivatives of zaomycin, derivatives of crystallomycin, derivatives of amphomycin, etc. This interpretation is necessary so that it is clear that dependent claims 5-7 further limit independent claim 1. This interpretation also results in a clearer distinction between the instant claims and the claims of U.S. Patent No. 6,716,962. If the examiner's interpretation of the claim language is incorrect, Applicants are requested to inform the examiner.

The statement of common ownership set forth in the paragraph bridging pages 8 and 9 of the response is not acceptable because it discusses common ownership between parent application 09/948,374 and U.S. Patent No. 6,511,962, whereas the requirement was to show common ownership between the claimed invention of this application and U.S. Patent No. 6,511,962 at the time the invention "in this application" was made. The invention in this application is different (although perhaps not unobviously different) than the invention in parent application 09/948,374, and therefore Applicants' statement of common ownership does not satisfy the requirement. Accordingly, U.S. Patent No. 6,511,962 remains available as prior art under 35 U.S.C. 103(a).

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Even upon submission of an acceptable statement of common ownership, U.S. Patent No. 6,511,962 will still be available as anticipatory prior art under 35 U.S.C. 102(e) and the rejection set forth in section 7 above will be maintained. As shown by Hayward et al (U.S. Patent Application Publication 2005/0288222) at paragraph [0048]; Bajaj (U.S. Patent No. 6,624,289) at column 6, lines 24-27; and Pierson, III et al (U.S. Patent No. 6,538,028) at column 11, lines 12-16; "derivative" is defined broadly in the art, and in light of these broad definitions, the current claim language does not distinguish over the laspartomycin taught by the '962 patent.

The rejections over Heinemann et al (U.S. Patent No. 3,126,317) set forth in the previous Office action are withdrawn. Heinemann et al teach extracting amphomycin from an aqueous solution acidified to a pH of 1.95 to 3.5 (see, e.g., Examples IV-VI and claim 3), which is below amphomycin's pI of 3.5-3.6 (see column 4, lines 9-10). This is the opposite of what is required by Applicants' claims, and does not suggest extracting from an aqueous solution having a pH higher than the pI of amphomycin.

10. Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

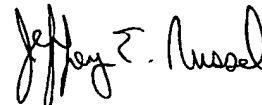
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

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JRussel

April 4, 2006